



Facility Establishment Identifiers

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History

- Central File Numbers – prior to 2000
- FEI – Facility establishment Identifier
 - ORA – internal
- Passage of FDASIA – signed July 9, 2012 specifies use of a Unique Facility Identifier
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FEI

- 10 digit Facility identifiers starting in 2000
 - Old CFN are retained
- Main purpose
 - Identification of the establishment
 - Maintenance of an establishments record of operations & products
- FEI – Firm establishment identifier
 - inspectional history
 - Including history generated with CFN

Generation of FEI

- Imports
- Registration
 - Districts are responsible for Domestic sites
 - OMPTO (formerly DFI) is responsible for Foreign
 - OFFO (formerly DFI) is responsible for Foreign CVM
- Applications (ANDA's, etc.)

Center & Field Responsibilities

- Centers
 - Registration & Self - Identification
 - DUNs
 - FEI
 - Registration
 - Notify Districts for FEI
 - Foreign sites - Notification to OMPTO for FEI



OEI Coordinators

- District – POC
- New Foreign POC

Roles – generating

Merging

Clarifications

Establishments

- Business or other entity (handles products or performs activities subject to FDA jurisdiction)
 - one owner
 - one geographic location *
 - May be more than One Center

* Separate buildings in close proximity **IF** the activities are closely related, same local mgt, & are capable of being inspected at the same time.

Establishments (cont.)

- Two or more business enterprises (separate legal entities)
 - May be at the same address
 - Require separate FEI numbers

General Rules & Guidance

- Firm moves – address change
 - Retain FEI
- Name change
 - Retain FEI
- Acquisitions
 - Retain FEI

Registration

- Requires a DUNs & FEI
- Obtain or clarify the FEI
 - Clarifying the operations (sterile, solid oral dosage)
- Update the on-line registration

FEI

- Updated in the on-line registration
- Referenced with import records
- Duplicates –
 - Determination (history, registration etc.)
 - Merge



FAQs

- Merge
 - Factors to consider
 - Imports
 - Registration
 - History of inspections
- Corporate Headquarters



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